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Substitute for form 1449A/PTO

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/706,243
Filing Date	November 12, 2003
First Named Inventor	Robert S. Feldstein
Group Art Unit	1616
Examiner Name	George, Konata M.
Attorney Docket Number	PDT 103 CON (3)

Sheet 1 of 10

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		4,153,689		Hirai	05-08-1979	
		4,196,196		Tiholiz	04-01-1980	
		4,211,769		Okada	07-08-1980	
		4,294,829		Suzuki	10-13-1981	
		4,659,696		Hirai	04-21-19	
		4,946,828		Markussen	08-07-1990	
		5,006,343		Benson	04-09-1991	
		5,042,975		Chien	08-27-1991	
		5,204,108		Illum	04-20-1993	
		5,354,562		Platz	10-11-1994	
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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		EP	0/069/715		Draco AB	01-12-1983		
		EP	0/122/036		Teijin Ltd	10-17-1984		
		EP	0/237/507		Draco AB	09-16-1987		
		EP	0 220 958 A2		Eli Lilly and Company	05-06-1987		
		EP	0/360/340		Akzo	03-28-1990		
		EP	0/364/235		Toyo Jozo Kabushiki	04-18-1990		
		EP	0/606/486		Teijin Ltd.	12-23-1993		

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		5,503,852		Steiner et al.	04-02-1996	
		5,514,646		Chance, et al.	05-07-1996	
		5,547,929		Anderson Jr. et al.	08-20-1996	
		5,562,909		Allcock, et al.	10-08-1996	
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		5,849,322		Ebert, et al.	12-15-1998	
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		EP	0655237		Hoechst AG	03-26-1996		
		EP	0748213		Inhale Therapeutic Sys	12-18-1996		
		EP	1/114/644		Genetech, Inc.	07-11-2001		
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		PCT	WO 90/13285		Enzytech, Inc	11-15-1990		

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		5,976,569		Milstein	11-02-1999	
		5,985,309		Edwards, et al.	11-16-1999	
		6,051,256		Platz, et al.	04-18-2000	
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		6,254,854		Edwards, et al.	07-03-2001	
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		PCT	WO 91/16882		Lipsome Technology	11-14-1991		
		PCT	WO 92/04069		Aktiebolaget astra	03-1992		
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		PCT	WO 95/11666		Coordinated Drug	05-04-1995		

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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 95/31979		R.P Scherer International	11-30-1995		
		PCT	WO 95/34294		Hamilton, Brook, Smith, & Reynolds P.C. and Yissum	12-21-1995		
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		PCT	WO 97/49386		Peptide Delivery Systems	12-31-1997		

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		PCT	WO 99/52506		Aventis Research & Technologies	10-21-1999		
		PCT	WO 01/00654		Steiner	01-2001		
		PCT	WO 01/07107		PharmaceuticalDiscovery Corporation	02-01-2001		
		PCT	WO 03/057170		Emisphere Technologies	07-17-2003		

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		2004/0077528		Steiner	04-22-2004	
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		PCT	WO 03/086345		Atrix Laboratories, Inc.	10-23-2003		
		PCT	WO 03/094951		Novo Nordisk As	11-20-2003		
		PCT	WO 04/056314		Nastech Pharmaceutical Company Inc	07-08-2004		
		PCT	WO 05/089722		Biodel , Inc	09-29-2005		
		PCT	04/075919		Medtronic Minimed, Inc	09-10-2004		
		PCT	02/11676		DMI Biosciences, Inc.	02-14-2002		

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OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
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		BAUER, et al., "Assessment of beta-adrenergic receptor blockade after isamoltane, a 5-HT ₁ -receptor active compound, in healthy volunteers," <i>Clin. Pharmacol Ther</i> 53:76-83 (1993).	
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		ENGELGAU, et al., "Screening for type 2 diabetes," <i>Diabetes Care</i> 1563(23):1-31 (2000).	

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		FESTA, et al., "LDL particle size in relation to insulin, proinsulin, and insulin sensitivity" <i>Diabetes Care</i> 22(10):1688-1693 (1999).	
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		Application Number	10/706,243		
		Filing Date	November 12, 2003		
		First Named Inventor	Robert S. Feldstein		
		Group Art Unit	1616		
		Examiner Name	George, Konata M.		
Sheet	9	of	10	Attorney Docket Number	PDT 103 CON (3)

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		LEAHY, "Beta-cell dysfunction in type II diabetes mellitus," <i>Curr. Opin. Endocrinol. Diabetes</i> 2(4): 300-306 (1995).	
		LEE, et al., "Development of an Aerosol Dosage Form Containing Insulin," <i>J. Pharm. Sci.</i> 65(4), 567-572 (1976).	
		LIAN, et al., "A self-complementary, self-assembling microsphere system: application for intravenous delivery of the antiepileptic and neuroprotectant compound felbamate," <i>J Pharm Sci</i> 89:867-875 (2000).	
		NAGAI, et al., "Powder Dosage Form of Insulin for Nasal Administration," <i>J. Control Rel.</i> , 1:15-22 (1984).	
		PFEIFFER, "Insulin secretion in diabetes mellitus," <i>Am. J. Med.</i> 70(3): 579-88 (1981).	
		PFUTZNER, et al., "Influence of small dose i.v., s.c. and pulmonary insulin treatment on prandial glucose control in patients with type 2 diabetes" <i>37th Annual Meeting of the EASD, Glasgow, 9-13 September 2001</i> 812 (2001) (abstract).	
		POLONSKY, et al., "Abnormal patterns of insulin secretion in non-insulin-dependent diabetes mellitus," <i>N. England J. Med.</i> 318(19): 1231-39 (1988).	
		PRABHU, et al. "A study of factors controlling dissolution kinetic of zinc complexed protein suspensions in various ionic species", <i>Int. J. Pharm.</i> , 217(1-2):71-8 (2001).	
		RASKIN, et al., "Continuous subcutaneous insulin infusion and multiple daily injection therapy are equally effective in type 2 diabetes" <i>Diabetes Care</i> 26:2598-2603 (2003).	
		ROSENSTOCK, et al., "Reduced hypoglycemia risk with insulin glargine: a meta-analysis comparing insulin glargine with human NPH insulin in type 2 diabetes", <i>Diabetes Care</i> , 28(4):950-5 (2005).	
		SCHLUTER, et al., "Pulmonary Administration of Human Insulin in Volunteers and Type I Diabetics", <i>Diabetes</i> , 33 (Suppl.): 298 (1984)	

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		SCHNEIDER, et al., "Stimulation by proinsulin of expression of plasminogen activator inhibitor type-I in endothelial cells" <i>Diabetes</i> 41(7):890-895 (1992).	
		WARREN, et al., "Postprandial versus preprandial dosing of biphasic insulin aspart in elderly type 2 diabetes patients" <i>Diabetes Research and Clinical Practice</i> 66:23-29 (2004).	
		WATERHOUSE, et al. "Comparative assessment of a new breath-actuated inhaler in patients with reversible airways obstruction." <i>Respiration</i> 59:155-158 (1992).	
		ZETHELIUS, et al., "Proinsulin is an Independent Predictor of Coronary Heart Disease" <i>Circulation</i> 105:2153-2158 (2002).	
		BERGE, et al. "Pharmaceutical Salts," <i>J. Pharmaceutical Sciences</i> 66(1):1-19 (1997).	
		HEINEMANN, et al. "Current Status of the development of inhaled insulin" <i>Br. J. Diabetes Vasc Dis</i> 4:295-301 (2004).	
		STEINER, et al. "Technosphere TM / Insulin- proof of concept study with new insulin formulation for pulmonary delivery" <i>Exp. Clin. Endocrinol. Diabetes</i> 110:17-21 (2002).	
		KOHLER, et al. "Non-radioactive approach for measuring lung permeability: inhalation of insulin," <i>Atemw Lungebrkhh</i> 13:230-232 (1987). (Original in German and English Translation attached).	
		RAZ, et al. "Pharmacodynamic and pharmacokinetics of dose ranging effects of oral versus s.c. regular insulin in Type 1 diabetic patients," <i>Fourth Annual Diabetes Technology Meeting</i> , Philadelphia, PA, 2004.	

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